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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,826	01/03/2002	Benjamin R. Yerxa	03678.0023.CNUS03	5357

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/041,826

**Applicant(s)**

YERXA ET AL.

**Examiner**

Patrick T. Lewis

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 7-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group II wherein **X** is oxygen,  $m + n = 2$ , and **B** and **B'** are a pyrimidine of general Formula **IIb** in Paper No. 4 dated July 8, 2003 is acknowledged. Election was made **without** traverse.

2. The restriction requirement as to the encompassed species of Group II is hereby withdrawn and claims directed to the species drawn to the variables **X**,  $m + n$ , and **B** and **B'** are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claims 3 and 5-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4 dated July 8, 2003.

***Applicant's Response dated December 16, 2003***

4. In the Response filed December 16, 2003, claims 1, 7-13, and 15 were amended. Applicant presented arguments directed to the rejection of claims 1-2, 4, 7-10, 12, 13, and 15 under 35 U.S.C. 112, second paragraph, and the rejection of claims 1, 2, 4, and 7-15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of prior U.S. Patent No. 5,900,407.

5. Claims 1-15 are pending. Claims 3 and 5-6 are withdrawn from further consideration as being drawn to a nonelected invention. An action on the merits of claims 1-2, 4, and 7-15 is contained herein below.

6. The rejection of claims 1-2, 4, 7-10, 12, 13, and 15 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment/arguments dated December 16, 2003.

7. The rejection of claims 1, 2, 4, and 7-15 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of prior U.S. Patent No. 5,900,407 has been rendered moot in view of applicant's amendments dated December 16, 2003.

***Claim Objections***

8. Claims 4 and 11-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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Regarding claim 4, independent claim 1 is already limited to the use of a compound of Formula II.

Regarding claims 11-13, claim 9 limits the administration of a liquid or liquid suspension of Formula II via nose drops, nasal spray, or nebulized liquid to oral or nasopharyngeal airways. Claims 11-13 employ modes of administration outside the scope of claim 9.

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-2, 4, and 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Variables  $R_1$  and  $R_2$  of Formula IIa have not been defined by the claims.

Claim 8 recites the limitation "said ocular surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-2, 4, and 7-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,900,407. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The difference between the instantly claimed method of enhancing drainage of the lacrimal system and the method of stimulating tear secretion of the '407 patent is that the method of the '407 patent is not limited to the use of the dinucleotide of Formula II. The claims of '407 and the instant invention overlap substantially, and to issue a patent to the claims of the instant application would be to extend the patent term for subject matter patented in '407. Although the two inventions are drawn to a different effect, they are not patentably distinct.

13. Claims 1-2, 4, and 7-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/010,055. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The difference between the method of the instant application and the method of the '055 application is that the instant application is drawn to a method of enhancing drainage of the lacrimal system; however one of ordinary skill in the art at the time of the

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invention would have a reasonable expectation of success of enhancing drainage of the lacrimal system employing the method of the '055 application since both methods employ the same nucleotide (compound of Formula II) and methodological steps (administration of a compound of Formula II to the eyes). Likewise, one of ordinary skill in the art at the time of the invention would have a reasonable expectation of success in employing the method of the instant application to stimulate tear secretion and mucin production in the eye. Although the two inventions are drawn to a different effect, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

14. Claims 1-15 are pending. Claims 1-2, 4, and 7-15 are rejected. Claims 3 and 5-6 are withdrawn from further consideration as being drawn to a nonelected invention. No claims are allowed.

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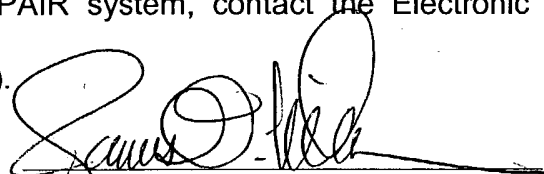
### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



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ptl  
March 15, 2004